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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,564	03/11/2004	Darin R. Okerlund	144726	2563

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EXAMINER	
WEATHERBY, ELLSWORTH	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/708,564	OKERLUND ET AL.	
	Examiner	Art Unit	
	Ellsworth Weatherby	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-5 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 4, 7 and 8 of copending Application No. 10/063064. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The application claim is merely broader than the copending Application claim. See *In re Goodman,* 11 F.3d 1046, 29 USPQ2d2010 (Fed. Cir. 1993)

Claim Objections

3. Claim 5 is objected to because of the following informalities: Applicant recites, "said interior views" without proper antecedent basis for the limitation of interior views. Appropriate correction is required.

4. Claim 17 is objected to because of the following informalities: Applicant recites, "...so as to interior views of the coronary arteries and ventricles". This phrase appears to be missing a verb. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (PGPub. No. 2004/0210125).

Regarding claim 1, Chen et al. '125 teaches a method for planning a minimally invasive surgery [0007], the method comprising: obtaining acquisition data from a medical imaging system and generating a 3D model of the region of interest [0008]; identifying one or more anatomical landmarks on the 3D model [0012]; registering saved views of the 3D model on an interventional system and visualizing one or more saved views on the interventional system [0017]. Chen et al. '125 also teaches that the 3D model and the interior views are visualized through a display screen associated with the interventional system [0027]. Chen et al. '125 also teaches registering a surgical instrument on the interventional system [0073].

7. Claims 9, 11, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Keiadar (EP 1 182 619).

Keidar '619 discloses a method comprising for planning coronary surgeries [0014] comprising: obtaining acquisition data from a medical imaging system using a

protocol directed toward the coronary arteries and left ventricle [0002;0008]; using a 3D protocol to segment the data so as to visualize the coronary arteries and the left ventricle [0008; 0015]; generating a 3D model of the coronary arteries and the left ventricle of the patient [0008; 0015]; identifying one or more anatomical landmarks, or a plurality of image points on the 3D model [0009; 0015]; registering saved views of the 3D model on an interventional system [0009; 0015]; visualizing one or more of the saved registered saved views with the interventional system [0009]; and identifying from the 3D model orientation and any anomalies associated with the coronary arteries and the left ventricle [0008;0035]. Keidar '619 further teaches visualizing the 3D model and interior views through a display screen associated with the interventional system (fig. 1, ref. 36). Keidar '619 also teaches as prior art using computed tomography or ultrasound data to gather diagnostic data to be used in conjunction with a 3D model [0004]. Keidar '619 further teaches synchronizing the data acquisition with an EKG to compensate for heart motion [0027].

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-4, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. '125 in view of Keidar '619.

The examiner notes Applicants' admission in copending application 10/063,064 that post-processing software (such as Advanced Vessel Analysis (AVA)) for performing advanced vessel analysis, depositing seeds, using connectivity and performing region growing techniques is known in the are (specification, [0019]). Applicant also admits that other software tools are known in the art for performing post-processing further including volume rendering and landmark identification such as (VR) and (CARDIQ) (specificiation, [0020]).

Regarding claims 2-4 and 8, Chen et al. '125 teaches all the limitations of the claimed invention except for expressly teaching that the method further comprises identifying from the 3D model, orientation, size and dimensions of the coronaries and ventricles and using data acquisition protocols directed for imaging the coronary arteries and ventricles.

In the same field of endeavor, Keidar '619 teaches identifying from a 3D model, orientation, size and dimensions of the coronaries and ventricles [0012; 0023;0024]. Keidar '619 also teaches as prior art obtaining acquisition data that is implemented with protocols directed for imaging the coronary arteries and ventricles, and further using EKG gating to provide EKG synchronization to the imaging console and account for heart motion [0002;0024;0027].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chen et al. '125 with Keidar '619. The motivation to modify Chen et al. '125 with Keidar '619 would have been to accurately register the 3D cardiac model with the acquired diagnostic images of the heart. Further, regarding claim 4, it would

have been obvious to one of ordinary skill in the art at the time of the invention to use post processing software such as (AVA) and (CARDIQ) to process acquisition data as is known in the art as admitted by applicant.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. '125 in view of Veseley et al. (U.S. Patent No. 6,246,898).

Chen et al. '125 teaches all the limitations of the claimed invention except for expressly teaching that the method further includes measuring the size, extent and number of lesions in the coronary artery.

In the same field of endeavor, Veseley et al. '898 teaches determining the 3D topographical properties of lesions to in the coronary arteries (col. 22, lines 12-27). Here, the examiner has interpreted the limitations includes measuring the size, extent and number of lesions in the coronary artery to be met because identifying the topographical properties of lesions inherently includes identifying size, extent and number of lesions in the coronary artery, thereby allowing the physician to confidently make a diagnosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of Chen et al. '125 with Veseley et al. '898. The motivation to modify Chen et al. '125 with Veseley et al. '898 would have been to improve the diagnostic utility of Chen et al. '125 with no additional hardware and further to improve characterization of the diseased arteries.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619.

Regarding claim 10, Keidar teaches all the limitations of the claimed invention except for expressly teaching that the system utilizes post processing software to process the acquisition data so as to generate interior views of the coronary arteries and ventricles.

Here, the Examiner notes Applicants' admission in copending application 10/063,064 that post-processing software (such as Advanced Vessel Analysis (AVA)) for performing advanced vessel analysis, depositing seeds, using connectivity and performing region growing techniques is known in the art (specification, [0019]). Applicant also admits that other software tools are known in the art for performing post-processing further including volume rendering and landmark identification such as (VR) and (CARDIQ) (specification, [0020]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use post processing software such as (AVA) and (CARDIQ) to process acquisition data as is known in the art as admitted by applicant.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619 in view of Seeley et al. (U.S. Patent No. 6,856,827).

Keidar '619 teaches as prior art position sensing surgical tools and tracking them on the interventional system [0020-0022]. However, Keidar '619 does not expressly teach that the surgical instruments are registered on the interventional system.

In the same field of endeavor, Seeley et al. '827 more clearly teaches registering a surgical tool tip and then tracking the tool in relation to the registration point (col. 3, lines 19-37).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Keidar '619 to include the tool registration method step of Seeley et al. '827. The motivation to modify Keidar '619 with Seeley et al. '827 would have been to track the tool in relation to the region of interest on the 3D model.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619 in view of Veseley et al. '898.

Keidar '619 teaches all the limitations of the claimed invention except for expressly teaching that the method further includes measuring the size, extent and number of lesions in the coronary artery.

In the same field of endeavor, Veseley et al. '898 teaches determining the 3D topographical properties of lesions to in the coronary arteries (col. 22, lines 12-27). Here, the examiner has interpreted the limitations includes measuring the size, extent and number of lesions in the coronary artery to be met because identifying the topographical properties of lesions inherently includes identifying size, extent and number of lesions in the coronary artery, thereby allowing the physician to confidently make a diagnosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Keidar '619 with Veseley et al. '898. The motivation to

modify Keidar '619 with Veseley et al. '898 would have been to improve the diagnostic utility of Keidar '619 with no additional hardware and further to improve characterization of the diseased arteries.

14. Claims 16-19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619 in view of Hunter et al (PGPub. No. 2004/0097806).

The examiner notes Applicants' admission in copending application 10/063,064 that post-processing software (such as Advanced Vessel Analysis (AVA)) for performing advanced vessel analysis, depositing seeds, using connectivity and performing region growing techniques is known in the art (specification, [0019]). Applicant also admits that other software tools are known in the art for performing post-processing further including volume rendering and landmark identification such as (VR) and (CARDIQ) (specificiation, [0020]).

Keidar '619 teaches a method for planning a treatment of the heart comprising obtaining acquisition data from a cardiac computed tomography imaging system using a protocol directed toward the coronary arteries and left ventricle, and further using EKG gating to synchronize acquisition to compensate for heart motion [0002; 0006; 0027]; segmenting the acquisition data using a 3D protocol so as to visualize the heart, including interior views [0008; 0015]; generating a 3D model of the coronary arteries and left ventricle of the patient [0009; 0016]; identifying from the 3D model, orientation and any anomalies associated with the coronary arteries and the left ventricle [0012; 0013; 0014].

Keidar '619 teaches as prior art using fluoroscopy [0002], but does not expressly teach further registering saved views of the 3D model on a fluoroscopy system and visualizing one or more saved views of the 3D model on a fluoroscopy system.

In the same field of endeavor, Hunter et al. '806 teaches registering saved views of a 3D model on a fluoroscopy system and visualizing one or more of the registered saved views with the fluoroscopy system [0068]. Hunter et al. '806 further teaches co displaying images on a fluoroscopy image [0068]. Hunter et al. '806 also teaches obtaining EKG gated acquisition data [0056].

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keidar '619 with Hunter et al. '806. The motivation to modify Keidar '619 with Hunter et al. '806 would have been to assist the physician to assimilate the position of the catheter's tip where the catheter's tip is projected on a plane traversing the specific location at a predetermined orientation, so as to enable the physician to evaluate the distance between the catheter's tip and the plane. Further, regarding claim 17, It would have been obvious to one of ordinary skill in the art at the time of the invention to use post processing software such as (AVA) and (CARDIQ) to process acquisition data as is known in the art as admitted by applicant.

15. Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619 in view of Hunter et al. '806 as applied to claim 16 above, and further in view of Seeley et al. '827.

Keidar '619 in view of Hunter et al. '806 teaches all the limitations of the claimed invention including tracking the position of a catheter (Keidar '619, [0020-0022]). Keidar in view of Hunter et al. '806 does not expressly that the surgical instruments are registered on the interventional system.

In the same field of endeavor, Seeley et al. '827 more clearly teaches registering a surgical tool tip and then tracking the tool in relation to the registration point (col. 3, lines 19-37).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keidar '619 in view of Hunter et al. '806 with the tool registration method of Seeley et al. '827. The motivation to modify Keidar '619 in view of Hunter et al. '806 with Seeley et al. '827 would have been to track the tool in relation to the region of interest on the 3D model.

16. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619 in view of Hunter et al. '806 and Seeley et al. '827 as applied to claim 20 above, and further in view of Vesely et al. '898.

Keidar '619 in view of Hunter et al. '806 and Seeley et al. '827 teaches all the limitations of the claimed invention except for expressly teaching that the method further includes measuring the size, extent and number of lesions in the coronary artery.

In the same field of endeavor, Veseley et al. '898 teaches determining the 3D topographical properties of lesions to in the coronary arteries (col. 22, lines 12-27). Here, the examiner has interpreted the limitations includes measuring the size, extent

and number of lesions in the coronary artery to be met because identifying the topographical properties of lesions inherently includes identifying size, extent and number of lesions in the coronary artery, thereby allowing the physician to confidently make a diagnosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Keidar '619 in view of Hunter et al. '806 and Seeley et al. '827 with Veseley et al. '898. The motivation to modify Keidar '619 in view of Hunter et al. '806 and Seeley et al. '827 with Veseley et al. '898 would have been to improve the diagnostic utility of Chen et al. '125 with no additional hardware and further to improve characterization of the diseased arteries.

17. Claims 22-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619 in view of Shelden et al. (U.S. Patent No. 4,638,798).

The examiner notes Applicants' admission in copending application 10/063,064 that post-processing software (such as Advanced Vessel Analysis (AVA)) for performing advanced vessel analysis, depositing seeds, using connectivity and performing region growing techniques is known in the art (specification, [0019]). Applicant also admits that other software tools are known in the art for performing post-processing further including volume rendering and landmark identification such as (VR) and (CARDIQ) (specificiation, [0020]).

Keidar '619 teaches a method for planning a minimally invasive cardiac surgery comprising: a medical imaging system for generating acquisition data with protocols

directed for imaging the coronary arteries and ventricles [0002; 0008]; an image generation subsystem for receiving the acquisition data and generating one or more images of the coronary arteries and the left ventricle of the patient [0008; 0015]; an operator console for identifying one or more anatomical landmarks on the one or more images [0009; 0031]; and a workstation for registering saved views of the 3D model on an interventional system [0009; 0031]. Keidar '619 further teaches synchronizing the data acquisition with an EKG to compensate for heart motion [0027].

Although Keidar '619 teaches mapping the heart for determination of the locations of diseased tissue [0035], Keidar '619 does not expressly teach that the interventional system is configured for visualizing the one or more registered saved views and quantifying distance and location information for a cardiac point of interest, and identifying an incision location and path for MIDCAB based on the quantified distance and location information for the cardiac point of interest.

In the same field of endeavor, Shelden et al. '798 teaches visualizing one or more registered saved views and quantifying distance and location information for a cardiac point of interest, and identifying an incision location and path for minimally invasive surgery based on the quantified distance and location information for the cardiac point of interest (col. 13, line 14 -- col. 14, line 7). Shelden et al. '798 also teaches a display screen associated with the interventional system for visualizing 3D perspective views (col. 13, line 14 -- col. 14, line 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keidar '619 with Shelden et al. '798. The motivation to modify Keidar

'619 with Shelden et al. '798 would have been to use the targeted invasive procedure of Shelden et al. '798 to proved therapy to the diseased tissue that is identified by the system of Keidar '619. Further, regarding claim 24, it would have been obvious to one of ordinary skill in the art at the time of the invention to use post processing software such as (AVA) and (CARDIQ) to process acquisition data as is known in the art as admitted by applicant.

18. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar '619 in view of Shelden et al. '798 as applied to claim 22 above, and further in view of Seeley et al. '827.

Keidar '619 in view of Shelden et al. '798 teaches all the limitations of the claimed invention including tracking a tool to a surgical site [Keidar '619, 0020-0022], however Keidar '619 in view of Shelden et al. '798 does not expressly teaching that the interventional system is configured for registering MIDCAB instrument therewith.

In the same field of endeavor, Seeley et al. '827 more clearly teaches registering a surgical tool tip and then tracking the tool in relation to the registration point (col. 3, lines 19-37).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Keidar '619 in view of Shelden et al. '798 with the tool registration method of Seeley et al. '827. The motivation to modify Keidar '619 in view of Shelden et al. '798 with Seeley et al. '827 would have been to track the tool in relation to the target in the 3D model.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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